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5. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The Assigned 510(k) number is K061559.

Submitter's Identification:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
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Date Prepared: May 29, 2006

Contact Person:

Edward Tung, Ph.D.
V.P., Regulatory Affairs

Proprietary Name of the Device:

ACON Urinalysis Reagent Strips

Common Name:

Urinalysis Reagent Strips

Regulation Section and Classification:

21 CFR § 862.1340	Urinary Glucose (Non-Quantitative) Test System
21 CFR § 862.1115	Urinary Bilirubin and its Conjugates (Non-Quantitative) Test System
21 CFR § 862.1435	Ketones (Non-Quantitative) Test System
21 CFR § 864.6550	Occult Blood Test
21 CFR § 862.1550	Urinary pH (Non-Quantitative) Test System
21 CFR § 862.1645	Urinary Protein or Albumin (Non-Quantitative) Test System
21 CFR § 862.1785	Urinary Urobilinogen (Non-Quantitative) Test System
21 CFR § 862.1510	Nitrite (Non-Quantitative) Test System

21 CFR § 864.7675 Leukocyte Peroxidase Test
21 CFR § 862.1095 Ascorbic Acid Test System
Class I: Urinary Leukocytes, Urinary pH, Nitrite, Urinary Protein, Ketones, Urinary Urobilinogen Urinary Bilirubin, Specific Gravity and Ascorbic Acid

Class II: Urinary Glucose and Occult Blood

Product Code:

JIL	Urinary Glucose (non-quant.) test system
JIO	Blood, Occult, Colorimetric, in urine
LJX	Test, Urine Leukocyte
CEN	Urinary, pH (non-quant.)
JMT	Nitrite (urinary, non-quant.) test system
JIR	Protein or Albumin (urinary, non-quant.) test system
JIN	Ketones (urinary, non-quant.) test system
CDM	Urinary Urobilinogen (non-quant.) test system
JJB	Urinary Bilirubin & its conjugates (urinary, non-quant.) test system
JMA	Acid, Ascorbic, 2, 4-Dinitrophenylhydrazine (Spectrophotometric)

Medical Specialty:

Clinical Chemistry

Predicate Device:

Multistix 10 SG Reagent Strips for Urinalysis, K905396
Bayer Corporation, marketed by Bayer Corporation, located at Elkhart, IN 46515, USA.

QuickVue UrinChek 10+SG, K861255
Quidel Corporation, marketed by Quidel Corporation, located at San Diego, CA 92121, USA.

Device Description:

The ACON Urinalysis Reagent Strips are urine test strips of which Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocyte reagent pads are affixed onto the plastic strips. The reagent pads react with the urine and provide a visible color reaction. Results are obtained by direct comparison of the test strip with the color blocks printed on the bottle label. The product is packaged with a drying agent in a plastic bottle. The entire reagent strip is disposable when the

disposal directions are followed exactly. Laboratory instrumentation is not required. These tests are intended for professional use with human urine.

Intended Use:

The ACON Urinalysis Reagent Strips are for qualitative and semi-quantitative detection of one or more of the following analytes in urine: Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes and Ascorbic acid. The ACON Urinalysis Reagent Strips (Urine) are for single use in professional near-patient (point-of-care) and centralized laboratory locations. The strips are intended for use in screening at-risk patients to assist diagnosis in the following areas:

- Kidney function
- Urinary track infections
- Carbohydrate metabolism (e.g. diabetes mellitus)
- Liver function
- Acid-base balance
- Urine concentration

The results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed. The test is to be read visually. It is intended for professional use only.

Tests Principles:

Glucose: This test is based on the enzymatic reaction that occurs between glucose oxidase, peroxidase and chromogen. Glucose if first oxidized to produce gluconic acid and hydrogen peroxide in the presence of glucose oxidase. The hydrogen peroxide reacts with potassium iodide chromogen in the presence of peroxidase. The extent to which the chromogen is oxidized determines the color which is produced, ranging from green to brown. Low amounts of glucose are normally excreted in urine. Glucose concentrations as low as 100 mg/dL, read at either 10 or 30 seconds, may be considered abnormal if results are consistent.

Bilirubin: This test is based on azo-coupling reaction of bilirubin with diazotized dichloroaniline in a strongly acidic medium. Varying bilirubin levels will produce a pinkish-tan color proportional to its concentration in urine. In normal urine, no bilirubin is detectable by even the most sensitive methods. Even trace amounts of bilirubin require further investigation. Atypical results (colors different from the negative or positive color blocks shown on the color chart) may indicate that bilirubin-derived bile pigments are present in the urine specimen, and are possibly masking the bilirubin reaction.

Ketone: This test is based on ketones reacting with nitroprusside and acetoacetic acid to produce a color change ranging from light pink for negative results to a darker pink or purple color for positive results. Ketones are normally not present in urine. Detectable ketone levels may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate metabolism situations, ketones appear in the urine in excessively high concentration before serum ketones are elevated.

Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration to green and yellow-green in urine of increasing ionic concentration. Randomly collected urine may vary in specific gravity from 1.003-1.035. Twenty-four hour urine from healthy adults with normal diets and fluid intake will have a specific gravity of 1.016-1.022. In cases of severe renal damage, the specific gravity is fixed at 1.010, the value of the glomerular filtrate.

Blood: This test is based on the peroxidase-like activity of hemoglobin which catalyzes the reaction of cumene-hydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange to green to dark blue. Any green spots or green color development on the reagent area within 60 seconds is significant and the urine specimen should be examined further. Blood is often, but not invariably, found in the urine of menstruating females.

pH: This test is based on a double indicator system which gives a broad range of colors covering the entire urinary pH range. Colors range from orange to yellow and green to blue. The expected range for normal urine specimens from newborns is pH 5-7. The expected range for other normal urine specimens is pH 4.5-8, with an average result of pH 6.

Protein: This reaction is based on the phenomenon known as the "protein error" of pH indicators where an indicator that is highly buffered will change color in the presence of proteins (anions) as the indicator releases hydrogen ions to the protein. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow to yellow-green for negative results and green to green-blue for positive results. 1-14 mg/dL of protein may be excreted by a normal kidney. A color matching any block greater than trace indicates significant proteinuria.

Urobilinogen: This test is based on a modified Ehrlich reaction between p-diethylaminobenzaldehyde and urobilinogen acid in strongly acidic medium to produce

a pink color. Urobilinogen is one of the major compounds produced in heme this test is 0.2-1.0 mg/dL (3.5-17 μmol/L). A result of 2.0 mg/dL (35 μmol/L) may be of clinical significance, and the patient specimen should be further evaluated.

Nitrite: This test depends upon the conversion of nitrate to nitrite by the action of Gram negative bacteria in the urine. In an acidic medium, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. The diazonium compound in turn couples with 1 N-(1-naphthyl)-ethylenediamine to produce a pink color. Nitrite is not detectable in normal urine. The nitrite area will be positive in some cases of infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test ranges from as low as 40% in cases where little bladder incubation occurred, to as high as approximately 80% in cases where bladder incubation took place for at least 4 hours.

Leukocytes: This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxy pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple color. Normal urine specimens generally yield negative results. Trace results may be of questionable clinical significance. When trace results occur, it is recommended to retest using a fresh specimen from the same patient. Repeated trace and positive results are of clinical significance.

Ascorbic acid: This test involves decolorization of Tillmann's reagent. The presence of ascorbic acid causes the color of the test field to change from blue-green to orange.

Substantial Equivalence:

The ACON Urinalysis Reagent Strips are substantially equivalent to the Bayer Multistix 10 SG Reagent Strips for Urinalysis (K905396) and the Quidel QuickVue UrinChek 10+SG (K861255).

Characteristic of the ACON Urinalysis Reagent Strips are compared with the Bayer Multistix 10 SG system (K905396) in the following table:

Area of Comparison	ACON Urinalysis Reagent Strips	Bayer Multistix 10 SG Reagent Strips for Urinalysis (K905396)
Intended Use	Professional use in point-of-care urine testing	Same
Target Population	Patients of physicians, hospitals, and clinics	Same
Intended Specimen	Urine	Same

Material Provided	Plastic strips affixed with several separate reagent areas.	Same
Storage	2 to 30°C	15 to 30°C
Test Time	Varies from 30 Seconds to 2 Minutes	Same
Glucose Methodology	Based on the enzymatic reaction that occurs between glucose oxidase, peroxidase and chromogen. Glucose if first oxidized to produce gluconic acid and hydrogen peroxide in the presence of glucose oxidase. The hydrogen peroxide reacts with potassium iodide chromogen in the presence of peroxidase. The extent to which the chromogen is oxidized determines the color which is produced, ranging from green to brown.	Same
Bilirubin Methodology	Based on azo-coupling reaction of bilirubin with diazotized dichloroaniline in a strongly acidic medium. Varying bilirubin levels will produce a pinkish-tan color proportional to its concentration in urine.	Same
Ketone Methodology	Based on ketones reacting with nitroprusside and acetoacetic acid to produce a color change ranging from light pink for negative results to a darker pink or purple color for positive results.	Same
Specific Gravity Methodology	Based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration to green and yellow-green in urine of increasing ionic concentration.	Same
Blood Methodology	Based on the peroxidase-like activity of hemoglobin which catalyzes the reaction of cumene-hydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange to green to dark blue.	Same
pH Methodology	Based on a double indicator system which gives a broad range of colors covering the entire urinary pH range. Colors range from orange to yellow and green to blue.	Same

Protein Methodology	Based on the phenomenon known as the "protein error" of pH indicators where an indicator that is highly buffered will change color in the presence of proteins (anions) as the indicator releases hydrogen ions to the protein. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow to yellow-green for negative results and green to green-blue for positive results.	Same
Urobilinogen Methodology	Based on a modified Ehrlich reaction between p-diethylamino-benzaldehyde and urobilinogen acid in strongly acidic medium to produce a pink color.	Same
Nitrite Methodology	This test depends upon the conversion of nitrate to nitrite by the action of Gram negative bacteria in the urine. In an acidic medium, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. The diazonium compound in turn couples with 1 N-(1-naphthyl)-ethylenediamine to produce a pink color.	Same
Leukocyte Methodology	This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxy pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple color.	Same

Area of Comparison	**ACON Urinalysis Reagent Strips**	**Quidel QuickVue UrinChek 10+SG (K861255)**
Ascorbic Acid Methodology	This test involves decolorization of Tillmann's reagent. The presence of ascorbic acid causes the color of the test field to change from blue-green to orange.	Same

Discussion of Clinical Tests Performed:

The clinical studies were conducted at Beta sites using the ACON Urinalysis Reagent Strips (Section 20, page 56 of this submission). Clinical data were presented evaluating clinical accuracy of results. Clinical study results indicate that the intended users were able to obtain comparable testing data when using the ACON Urinalysis Reagent Strips and the legally marketed Bayer Multistix 10 SG Reagent Strips for Urinalysis (K905396) and the Quidel QuickVue UrinChek 10+SG (K861255).

Conclusion:

The performance characteristics of the ACON Urinalysis Reagent Strips were verified by sensitivity study, reproducibility study, interference studies, temperature flex study, and stability studies. Testing results indicate that the ACON Urinalysis Reagent Strips are robust and can perform satisfactorily when used according to the "Directions for Use" statement specified in the package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 11 2006

ACON Laboratories, Inc.
c/o Mr. Martin O'Connor
Germaine Laboratories, Inc.
4139 Gardendale Center, #101
San Antonio, TX 78229

Re: k061559
Trade/Device Name: ACON™ Urinalysis Reagent Strips
Regulation Number: 21 CFR§862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: Class II
Product Code: JIL, JIO, LJX, CEN, JMT, JIR, JIN, CDM, JJB, JMA
Dated: July 14, 2006
Received: July 18, 2006

Dear Mr. O'Connor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE

510(k) Number (if known): K061559

Device Name: ACON Urinalysis Reagent Strips

Indications for Use:

The ACON Urinalysis Reagent Strips (Urine) are for qualitative and semi-quantitative detection of one or more of the following analytes in urine: Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes and Ascorbic Acid.

The ACON Urinalysis Reagent Strips (Urine) are for single use in professional near-patient (point-of-care) and centralized laboratory locations. The strips are intended for use in screening at-risk patients to assist diagnosis in the following areas:

- Kidney function
- Urinary track infections
- Carbohydrate metabolism (e.g. diabetes mellitus)
- Liver function
- Acid-base balance
- Urine concentration

The results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed. The test is to be read visually. It is intended for professional use only.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(Optional) K061559